



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

24

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,657	03/16/2004	Kazutami Sakamoto	250521US0CONT	1130
22850	7590	07/14/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			WILLIAMS, LEONARD M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,657	SAKAMOTO ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The examiner notes that this is a continuation of application 10/055,951 filed on 01/28/2002 now abandoned.

Response to Amendment

The examiner notes the entering of the amendment of 4/28/2005 canceling claims 1-8 and adding new claims 9-30.

Applicant's arguments with respect to claims 1-8 have been considered but are moot due to the applicant's amendment.

The examiner wishes to address the arguments made in view of the in re Jansen reference. The examiner respectfully points out that the assertion of a sub-set of patients in need of treatment in the arguments of 04/28/2005 is met by the patient population designated by Baldacci as the compositions are identical and in the same effective amounts relative to the total weight of the compositions, thus the patient population of Baldacci is receiving the same compounds in the same amounts and thus are inherently having their nitric oxide production enhanced and/or their nitric oxide synthase production enhanced.

New ground(s) of rejection are set forth below.

Claim Rejections - 35 USC § 102

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-13, 16-24, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldacci (US Patent No. 4581371).

Baldacci, in col. 1 lines 15-35 and claim 1, teach a method for restoring depressed immunodefenses comprising administering to a patient having depressed immunodefenses an immunomodulating composition comprising L-arginine, L-lysine, and their salts with L-2-pyrrolidone-5-carboxylic acid anticipating the "...method of...comprising administering...a composition comprising at least one compound selected from the group consisting of pyrrolidonecarboxylic acid, a pyrrolidonecarboxylic acid salt, and a pyrrolidonecarboxylic acid derivative" of claims 9 and 20, the "...method...wherein said composition further comprises arginine..." of claims 10 and 21, the "...method...wherein said arginine is selected from..." of claims 11 and 22, the "...method...wherein said composition further comprises at least one medicine or cosmetic" of claims 12 and 23, and the "...method...wherein said composition has an activity..." of claims 13 and 24.

Baldacci, in col. 2 line 55 to col. 3 line 10, teach a pharmaceutical composition containing L-2-pyrrolidone-5-carboxylate of L-arginine (1 g, ~4% by weight), L-2-pyrrolidone-5-carboxylate of L-lysine (1g, ~4% by weight), potassium iodide, sodium benzoate, fructose, ascorbic acid, sodium metabisulfite, lemon flavor, and deionized

Art Unit: 1617

water anticipating the "...method...wherein said composition is a pharmaceutical composition...": of claims 16 and 27, the "...method...wherein said pharmaceutical composition is in a form..." of claims 17 and 28, the "...method... wherein said pharmaceutical composition further comprises..." of claims 18 and 29 and the "...method...wherein said pharmaceutical composition further comprises..." of claims 19 and 30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-15 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldacci as applied to claims 9-13, 16-24, and 27-30 above, and further in view of Noel (U.S. Patent No. 5141964).

Baldacci is as set forth above.

Baldacci does not teach cosmetic compositions in the form of a lotion, an emulsion, a gel, a cream, or an ointment.

Noel, in example 3, teaches a cosmetic composition comprising chitosan, gluconic acid, pyrrolidonecarboxylic acid (0.7% by weight), glucosamine HCl, arginine (0.6% by weight), and absorbed water.

Noel, in col. 2 lines 20-30, that the cosmetic compositions may be used to formulate creams, gels, milks, body emulsions, and liquid soaps.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the Baldacci compositions could be used in the formulations detailed in Noel as Noel demonstrates the use of Balducci's compounds as evidenced by Noel example 3. One would have been motivated to use Balducci's compounds in Noel's formulations in order to increase the immunomodulating activities of Noel's cosmetic skin preparations.

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

Art Unit: 1617

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

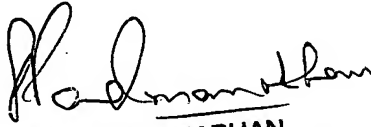
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER